K110958

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510(k) Summary
VersaJet II Hydrosurgery System

AUG - 1 2011

1. **Submitter:** Smith & Nephew, Inc.
970 Lake Carillon Drive, Suite 110
St. Petersburg, FL 33716

2. **Contact:** Laura D. Reynolds
Director, Regulatory Affairs
727-329-7702

3. **Date Prepared:** April 4, 2011

4. **Device Name:** VersaJet™ II Hydrosurgery System
Common Name: Pulse lavage with sharp debridement
Classification Name: Jet Lavage, 21 CFR 880.5475
Product Classification/Code: Class II / FQH

5. **Predicate Device Information:**

VersaJet Hydrosurgery System — 510(k) # K060782
Smith & Nephew, Inc.
970 Lake Carillon Drive, Suite 110
St. Petersburg, FL 33716

6. **Device Description:**

The VersaJet II Hydrosurgery System uses a pressurized stream of sterile fluid to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications. The device provides cutting, irrigation and evacuation in the same tool.

The stream of saline simultaneously washes the tissue surface and vacuums away foreign material, including contamination and infected and necrotic tissue from the wound. The debris and fluid are directed into the handpiece into a flexible tube, which carries the effluent to the drain or collection canister.

The system employs two basic system components: the reusable power console and the single-use, sterile handpiece and tubing assembly.

The primary change to the system is the design of the interface of the handpiece into the console. The new design is a simple, intuitive "key lock mechanism" design that improves the ease of connection of the handpiece to the console.

7. **Intended Use:**

The VersaJet II Hydrosurgery System is intended for wound debridement (acute and chronic wounds, burns), soft tissue debridement, and cleansing of the surgical site in applications in which, in the physicians judgment, require sharp debridement and pulsed lavage irrigation.

8. **Summary of Non-Clinical Testing:**

There have been no changes to the patient contacting components of the disposable handpiece. Biocompatibility has previously been completed in accordance with ISO 10993 and is on file at Smith & Nephew:

Evaluation Tests Conducted	**Result**
Cytotoxicity	Passed
Sensitization	Passed
Irritation	Passed

Design verification testing has been completed to document that all performance specifications have been met. The following table summarizes the testing that has been successfully completed.

Design Input Description	**Result**
No increase in weight when compared to current console.	Passed
Ability to load pump cartridge up or down (0° or 180°) without affecting performance and/or damaging pump or console.	Passed
Low noise level	Passed
Easy insertion and removal in a single attempt with positive feedback to user that the handpiece is engaged in the console.	Passed
Force to load and unload disposable mechanism should be no greater than current VERSAJET loading.	Passed
Effective Cutting levels (1 to 10) - console operation must provide equivalent pressures to the new handpiece cutting window equal to existing handpiece models and console.	Passed
The VersaJet II handpiece will operate using the footswitch when correctly connected to the console.	Passed
Transmission design provides reciprocating axial force to cartridge.	Passed
LED indicators on front panel are visible under normal OR conditions.	Passed
Footswitch provides the control signal to the console to activate the handpiece when depressed and deactivate when released.	Passed
The footswitch will provide the capabilities to control the (up/down) power level setting functions using designated push buttons on the footswitch.	Passed
Handpiece capable of completing 30 minutes average debridement procedure.	Passed
Handpiece is effective at all cutting power levels.	Passed

9. **Conclusions Drawn:**

Based on the results of design verification testing, it is concluded that the new VersaJet II system meets all defined performance specifications and is substantially equivalent to the currently marketed VersaJet Hydrosurgery System. The VersaJet II Hydrosurgery System is safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Laura Reynolds
Director Regulatory Affairs
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

AUG - 1 2011

Re: K110958
Trade/Device Name: VersaJet II Hydrosurgery System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: II
Product Code: FQH
Dated: July 15, 2011
Received: July 19, 2011

Dear Ms. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110958

Device Name: VersaJet II Hydrosurgery System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kwon for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110958